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EurEau's Contribution to the European Commission Strategic Approach on Pharmaceuticals in the Environment

Summary

Pharmaceuticals products are essential to our society's health and their use is likely to increase in the future due to a growing ageing population. EurEau wishes to contribute to the European Commission's Strategic Approach to pharmaceuticals in the environment by proposing an action plan that aims at reducing their discharges, emissions and losses into the aquatic environment.

EurEau has consistently advocated that a source control approach must be sought when facing challenges posed by chemical substances, since end-of-pipe solutions are not a sustainable option. Additional treatment of waste water is expensive and inefficient due to increased energy consumption; additional use of chemical substances combined with the production of non-wanted transformation products and increased sludge handling.

EurEau's action plan aims at involving stakeholders at different level: from the pharmaceutical industry, to doctors, to consumers. It proposes legislative measures as well as voluntary actions: everybody should play an active role in the strategic approach, taking ownership and accepting responsibility.

Why a Strategic Approach to pharmaceuticals intended for human use in the environment?

Pharmaceutical products intended for human use play an important role in our societies' health and wellbeing. The consumption of medications has been growing in the last decades and the environmental impact of pharmaceuticals has augmented in parallel, according to a 2010 report from the European Environment Agency. The situation is

likely to deteriorate further in the upcoming years due to the increasing demand of medications by a growing ageing population and the persistent and bio-accumulative characteristics of certain compounds.

Safe drinking water and sanitation has been recognised as a human right at the Rio+20 Conference in June 2013. EurEau's members are committed to make this human right a reality by providing high quality water and waste water services 24 hours, 7 days a week, 365 days a year.

Consumers do care about the quality of water, as shown by the 2012 Eurobarometer on "Attitudes of Europeans towards water": 84% of Europeans believe that chemical pollution is a threat to the water environment. EurEau expects pollutants in the water cycle to be one of the strategic topics water industry will have to be confronted with in the upcoming years.

Several research studies are currently being conducted to understand how serious of a threat pharmaceutical products pose to the aquatic environment and to human health. These studies are not only addressing active ingredients, but also the effects of degradation products and of mixtures. As some impacts on aquatic organisms have already been observed in field situation, the consideration of the problem should firstly address the impact on the aquatic environment, followed by potential impacts on water services. EurEau's members are concerned since, on the one hand, drinking water operators should be able to rely on drinking water resources in good status, while, on the other, the waste water operators clean waste waters containing pharmaceuticals but cannot remove all substances.

Regarding drinking water resources, EurEau stresses the importance of full implementation of Article 7 paragraph 3 of the Water Framework Directive by which Member States should explicitly consider the pollution of water bodies by pharmaceuticals also in view of the implementation of the no-deterioration clause laid down therein.

The 2013 review of the EU directive as regards priority substances in the field of water policy mandated the European Commission, in Art.8c, with the task of developing a strategic approach to pollution of water by pharmaceutical substances, thus giving application to Art.16.9 of the Water Framework Directive. The strategic approach shall include proposals as to take the environmental impacts of medicines into account in the procedure of placing medicinal products on the market. The European Commission should also propose measures to address the possible environmental impacts of pharmaceuticals, with a view to reducing discharges, emissions and losses into the aquatic environment.

When developing a strategic approach to pharmaceuticals, the European Commission will have to take into account environmental objectives, public health aspects and the cost-effectiveness of the measures proposed. EurEau Members are committed to provide water supply and sanitation at affordable prices and in a sustainable way to European citizens.

Therefore EurEau calls on the European Commission to develop a holistic approach that tackles problems at the source, by reducing emissions, discharges and losses of pharmaceutical products to the aquatic environment. Imposing new obligations at waste water treatment level, upgrading existing treatment plants, is a possibility that can be considered only in very specific circumstances, but it will never be the generic solution to the risks posed by pharmaceuticals all over Europe.

The increased energy consumption, the additional use of chemical substances, combined with the production of non-wanted transformation products and increased sludge handling, make the advanced treatments at the wastewater treatment plants a non-sustainable option to respond to the challenge arising from the presence of pharmaceutical products in the environment.

The costs of upgrading existing plants would make the service provided by wastewater utilities more expensive for users. Studies show that costs could increase by 18 to 70 € per person/per year, depending on the technology used, on the size of the plant and on the removal rate of pharmaceuticals.

By considering the advanced and often energy demanding treatments for pharmaceuticals at the wastewater treatment plants as the most immediate and straightforward solution, the wastewater sector would open the door to continuous and unsustainable upgrades in the future, whenever new problems arise from other emerging pollutants – instead of holistically tackling the problem at source. Many end-of-pipe solutions do not solve the environmental problem – but will only shift it. Furthermore it would result in decreasing public awareness and lowering decision makers' guard on new challenges the water sector has to face.

Key objectives of the EurEau's contribution to the Strategic Approach

EurEau's contribution to the European Commission's Strategic Approach to pharmaceuticals aims at proposing an action plan to tackle the presence of pharmaceuticals in the water cycle at the source. Although this paper addresses the presence of pharmaceuticals resulting from human uses, similar medicinal products for veterinary use are regularly administered to livestock. EurEau recognises that these practices add to the total loading of pharmaceuticals in the environment. In order to prevent or at least reduce inputs of pharmaceutical substances in water, a mix of measures is necessary, including voluntary actions and the improvement of specific legal frameworks.

With this contribution EurEau addresses, in the first place, decision makers at EU and national level. At the same time, it is targeted to a large audience in order to raise public awareness on the problem. The function of water treatment at the end-of-pipe and the role of the water sector should also be better communicated to citizens.

We are all in this together: other actors/partners

Together with the precautionary principle the polluter pays principle is one of the key elements underpinning the European environmental policy. The public debate in the 2013 review of the priority substances directive has shown diverging opinions when it comes to identifying who is the polluter in the case of pollution originating from pharmaceuticals. That is why the action plan of the EurEau's contribution of the Strategic Approach to pharmaceuticals involves the participation of a whole range of actors and is articulated in a series of measures of different nature.

For the specific function they carry out in our society's public health and care, pharmaceutical products are different from other chemical substances. They are subject to an authorisation at European level, through the European Medicines Agency (EMA), or separately for each country, at national level. The EMA authorisation procedure requires an environmental risk-assessment study to be conducted, although environmental risks cannot constitute grounds to refuse marketing authorisation of medicines for human use. The environmental risk assessment has not been published in the registration dossier by the EMA so far, so the impact of a pharmaceutical product on the environment is difficult to foresee for "downstream" actors that have to deal with pharmaceuticals after the authorisation is granted.

Some of EurEau's Members have conducted research projects on the topic, others have already engaged at national level with the different partners acting at the various levels in order to reduce emissions, discharges and losses of pharmaceutical products to the aquatic environment. Building on this experience, EurEau will actively seek cooperation and a committed exchange on the topic at European and Member States level with pharmaceutical industries associations, doctors associations, hospitals associations, pharmacists associations, patients associations, consumers associations, NGOs and decision makers. Everybody should play an active role in the strategy, take ownership and accept responsibility.

A framework for action for the next decade

In order to reduce emissions, discharges and losses of pharmaceutical products to the aquatic environment, EurEau proposes coherent actions to be taken at different levels.

1. Design level: development of green pharmacy

- a. More research programmes should be set up to encourage a long term approach based on the rational design of new pharmaceuticals, in order to address the environmental aspects of the whole life cycle of a compound like improved degradation or elimination through conventional effluent treatment from the very beginning.

2. Authorisation level

- b. The environmental risk assessment conducted on medicinal products, in the context of the marketing authorisation procedure, should be taken fully into account in the broader risk-benefit analysis whose criteria would also embrace the protection of water resources. The environmental risk assessment should consider the whole life cycle of the product.
- c. The environmental risk assessment conducted on medicinal products prior to the authorisation should be publicly available on the EMA website, through the European Public Assessment Report (EPAR).

3. Post-Authorisation level

- d. Post marketing monitoring by the producer (with third party peer review) is needed to gather data on the occurrence and on the behaviour of the medicinal ingredients, their degradation products and mixtures in the aquatic environment. Data should be made available upon request to parties with a legitimate interest and then be used to assess whether the marketing authorisation should be withdrawn.
- e. Pharmaceutical substances should be environmentally classified: the experience of the Stockholm County Council (“Environmentally classified pharmaceuticals”, 2009) could serve as a best practice for other European countries.

4. Marketing level

- f. The impact of medications on the environment should be easily recognised by the patients/consumers. An eco-label should be put on the packaging following the environmental classification of medicines.
- g. Packages should contain smaller doses of medications, as to avoid the risk that unused drugs be disposed by households inappropriately.

5. Hospital level

- h. Structures like hospitals and other healthcare institutions should put in place a special treatment of their wastewater, as to control pharmaceutical substances in water as early as possible upstream.

6. Healthcare professionals’ level: prescriptions and training

- i. Several medications are available at the counter or in the shelves without the need of prescription by a practitioner. Prescriptions should be compulsory for those medications with a high environmental impact, according to the eco-classification.
- j. Specific training programmes should be offered to healthcare professionals (medical practitioners as well as chemists/pharmacists) to make them aware of the hazard of medications and they should be encouraged to prescribe substitutes

that have less significant environmental impact between therapeutically equivalent compounds.

7. Households level: make consumers and patients more responsible

- k. Consumers associations and patients associations should also raise awareness on the environmental risks associated with the use of medications.
- l. Promoting healthier lifestyles would be desirable in order to decrease the consumption of certain types of medicines.
- m. Consumers' associations should also play a role in raising awareness on how to dispose of unused and expired drugs properly. In some Member States water utilities have been campaigning in co-operation with other relevant actors.
- n. To improve the management of unused medicine, "take back" schemes should be harmonised through the EU, as to render the process more obvious to consumers/patients, encouraging them to dispose of unused and expired drugs properly. Recollection systems have been required since 2004, but the implementation has been deficient in several Member States.

8. Wastewater treatment plants level

- o. EurEau has consistently reiterated that end-of-pipe treatments alone do not solve the problems, since pharmaceutical substances can be eliminated in waste water treatment plants only partly even with additional treatment steps. Furthermore, households outside sewer network as well as sewer overflows also play a role.
- p. Activated carbon and ozonation are considered most promising methods for pollutants removal. The best results are achieved by using a combination of an oxidation technique (e.g. ozone treatment) and a supplementary adsorption technique (activated carbon filtration): the average removal rate of all pharmaceuticals is around 90%.
- q. There is a need to study removal technologies aiming to develop cost-efficient and sustainable methods for pollutants removal. Water utilities are already doing a lot of research related to the treatment technologies.

9. Drinking Water level

- r. Drinking water operators will continue to monitor pharmaceuticals in the source water at the point of intake and they will continue their cooperation with the competent authorities on this matter.

Conclusions: The way forward

The EurEau's proposal to a Strategic Approach to pharmaceuticals is an attempt to deal with this type of emerging pollutants in a holistic way, trying to provide sustainable solutions to new challenges. Actors at different levels must take appropriate actions with

a view to reducing emissions, discharges and losses of pharmaceutical products to the aquatic environment.

EurEau welcomes further cooperation with other stakeholders and decision makers at EU and national level on this topic in order to implement the action plan.

About EurEau

EurEau is the voice of Europe's water sector. We represent drinking water and waste water service providers from 27 countries in Europe, from both the private and the public sector. With a direct employment of around 600 000 people, the European water sector makes a significant contribution to the European economy.

EurEau is the European Association of National Associations of Water Services. We bring national water professionals together to agree European water industry positions regarding the management of water quality, resource efficiency and access to water for Europe's citizens and businesses.



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